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**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION**

IN RE: DA VINCI SURGICAL ROBOT
ANTITRUST LITIGATION

THIS DOCUMENT RELATES TO:
[ALL ACTIONS]

Lead Case No.: 3:21-cv-03825-VC

**MOTION OF INTUITIVE
SURGICAL, INC. TO EXCLUDE
TESTIMONY OF DR. EUGENE
RUBACH**

Hearing Date: June 8, 2023
Hearing Time: 1:00 PM PST
Hearing Place: Courtroom 4

Judge: The Honorable Vince Chhabria

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NOTICE OF MOTION AND MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on June 8, 2023, at 1:00 p.m., or as soon thereafter as available, in the courtroom of the Honorable Vince G. Chhabria, located at 450 Golden Gate Avenue, Courtroom 4, 17th Floor, San Francisco, CA 94102, Defendant Intuitive Surgical, Inc. (“Intuitive”) will and hereby does move for an order excluding certain testimony of Dr. Eugene Rubach, who is proffered by plaintiffs as an expert witness.

This Motion is based on this Notice of Motion, the Memorandum of Points and Authorities, the accompanying Declaration of Cortlin Lannin and attached exhibits, any reply or other supplemental briefing and/or evidence submitted, and the oral argument of counsel.

MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION AND STATEMENT OF ISSUE

Intuitive moves pursuant to Rule 702 of the Federal Rules of Evidence to exclude certain opinions of Dr. Eugene Rubach, an expert witness proffered by plaintiffs to opine on various topics. As set forth below, several of Dr. Rubach’s opinions are beyond the scope of his surgical expertise, while others lack the threshold reliability required under *Daubert* and its progeny. The Court should exclude these opinions.

First, Dr. Rubach opines that the EndoWrist use limits are “arbitrary.” His sole support for this opinion is his personal anecdotal experience with some EndoWrists failing before their maximum number of uses and others that were rendered inoperative after the maximum number of uses, even though he believed they would “likely last much longer even without any servicing.” Dr. Rubach fails to consider and account for record evidence that Intuitive established (and the FDA cleared) the EndoWrist use limits based not on “arbitrary” criteria but rather on robust scientific testing. In the face of this mountain of genuine scientific evidence, a contrary view based on nothing more than anecdotal personal experience is inadmissible under the Federal Rules.

Second, Dr. Rubach opines that EndoWrist “repair restrictions” (his terminology for Intuitive’s—and FDA’s—position on the use of EndoWrists that have been remanufactured to reset use

limits without FDA clearance) are arbitrary, in part because he has generally found other kinds of repaired instruments to be “safe and effective.”¹ But the safety and effectiveness of a different medical instrument that has been genuinely repaired without any changes to its intended use is hardly a reliable predictor of whether the same can be said of a modified EndoWrist. Significantly, Dr. Rubach has never used a “repaired” EndoWrist before, and he conceded at his deposition that he could not comment on the effectiveness of such a device. And when questioned about his opinion that “there is no reason to treat EndoWrist instruments differently than their laparoscopic counterparts,” he acknowledged that he is not an engineer and is unable to offer a basis for that opinion either.

Third, Dr. Rubach opines that Intuitive is the “dominant force in the US robotic surgery market.” Dr. Rubach is not an economist; nor does he have other expertise that would qualify him to opine on complex economic questions. His opinion on this issue is nothing more than his uninformed *ipse dixit*.

Fourth, Dr. Rubach opines that hospitals need da Vinci systems to effectively recruit surgeons and to attract patients. However, Dr. Rubach has neither the credentials nor experience to support these opinions.

Fifth, Dr. Rubach discusses an earlier-generation “Zeus” robot and opines that, among other things, “surgeons” have leveled “widespread criticism” that the da Vinci system lacks the haptic feedback functionality of the Zeus robot. This “opinion” is based on nothing other than anecdotal hearsay reports and speculation on a subject about which he has no personal knowledge and should also be excluded.

¹ Toeing plaintiffs’ party line, Dr. Rubach uses the term “repair” throughout his report as if this case were about mere “repairs” to EndoWrists, as opposed to the more substantial *remanufacturing* of the instruments that FDA has repeatedly found to be involved when an EndoWrist is modified to have its use counter hacked and reset. Dr. Rubach is not, however, qualified to offer an opinion about whether such modifications constitute “repair” rather than “remanufacturing”; nor does he purport to do so. Indeed, in his deposition Dr. Rubach used the terms interchangeably. See, e.g., Lannin Dec. Ex. 3 at 106:17–24, 107:6–21.

Finally, Dr. Rubach offers the sweeping opinion that “doctors” and “physicians” everywhere often use drugs and medical devices “off-label.” However, these opinions are irrelevant to the issues actually presented in this case, and in any event Dr. Rubach lacks any reliable basis to speak on behalf of the profession in regards to off-label use.²

II. STATEMENT OF FACTS

Dr. Rubach is a general surgeon who practices in the State of New York. Lannin Dec. Ex. 1 ¶ 1. The majority of the operations he has performed over the course of his 17-year career “were done using minimally invasive techniques (both laparoscopic and robotic).” *Id.* ¶¶ 1, 2. Dr. Rubach claims to have extensive experience using the da Vinci surgical system. *Id.* ¶¶ 3, 7.

Dr. Rubach offers a variety of opinions, not all of which are the subject of this motion. Rather, this motion focuses on those of his opinions that he is unqualified to make and/or that lack any proper scientific or other reliable support in the record. This includes his opinions as to:

- The alleged arbitrariness of EndoWrist use limits. *See* Lannin Dec. Ex. 1 ¶¶ 12, 28–33, 35–36; *id.* Ex. 2 ¶¶ 3(e), 4–9, 30.
- The alleged arbitrariness of EndoWrist “repair restrictions.” *See id.* Ex. 1 ¶¶ 34–35; *id.* Ex. 2 ¶¶ 3(g), 7, 15–16, 18.
- Intuitive’s purported dominance of an alleged market for minimally invasive robotic surgery. *See id.* Ex. 1 ¶¶ 18, 21–23; *id.* Ex. 2 ¶¶ 3(a), 19(a).
- The marketing and recruiting implications for hospitals of having a da Vinci system. *See id.* Ex. 1 ¶¶ 9, 23–24; *id.* Ex. 2 ¶¶ 3(b), 9(b).
- The features of an earlier-generation “Zeus” robot and surgeons’ supposed “widespread criticism” that the da Vinci system lacks that robot’s tactile feedback functionality. *See id.* Ex. 1 ¶ 22.
- How physicians and doctors supposedly practice “off-label use.” *See id.* Ex. 2 ¶¶ 12–14.

III. ARGUMENT

Expert witness testimony must (1) come from a qualified expert; (2) be helpful to the factfinder; (3) be based on sufficient facts or data; (4) use reliable principles and methods; and (5) reliably apply

² For the avoidance of doubt, Intuitive reserves its right to raise additional objections to Dr. Rubach’s testimony at a later date. This brief focuses on key issues fit for resolution at this stage of the case.

those principles and methods to the facts of the case. Fed. R. Evid. 702. The court’s “gatekeeping” role requires evaluating both the reliability of the expert’s methods and the connection between their conclusions and the facts on which those conclusions are based. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). To evaluate an expert’s qualifications, courts look to the “expert’s knowledge, skill, experience, training, and education in the subject matter of his asserted expertise.” *United States v. Hankey*, 203 F.3d 1160, 1168 (9th Cir. 2000). The party proffering expert testimony has the burden of proving admissibility. *See Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592 n.10 (1993).

A. Dr. Rubach’s Opinions Regarding the Alleged Arbitrariness of EndoWrist Use Limits Should Be Excluded as Unreliable.

Dr. Rubach opines that EndoWrist use limits are “based on criteria which, in my opinion as a surgeon, are arbitrary and do not reflect whether the EndoWrist is suitable for clinical use.” Lannin Dec. Ex. 1 ¶ 33; *see also id.* ¶ 12; *id.* Ex. 2 ¶ 30. This opinion is based on his personal experience with EndoWrist instruments “fail[ing] before their 10th surgery,” while at other times he has “seen” the use counter render an “EndoWrist instrument unusable, even though it was lightly utilized in 10 previous patients and would likely last much longer even without any servicing.” *Id.* Ex. 1 ¶ 31; *see also id.* Ex. 2 ¶¶ 3(e), 5; *id.* Ex. 3 at 106:7–16. For the latter, he does not cite any rigorous inspection or other evaluation to support his speculation that the instruments “would likely last much longer.” *Id.* Ex. 1 ¶ 31. Dr. Rubach has not performed any scientific testing or analysis on this subject; his opinions are based on nothing more than a few examples in his personal experience where an EndoWrist’s assigned lives were too few or (perhaps) too many than he thinks they should have been.³

In fact, there is a plentiful record here of years of detailed scientific testing on the useful lives of EndoWrists. For example, Intuitive’s expert Dr. Robert Howe describes in detail the process Intuitive used to develop the EndoWrist use limits. *See id.* Ex. 4 ¶¶ 52–72. He notes that “[t]o verify that the design of EndoWrist instruments meets the proposed number of surgical uses, Intuitive conducts life

³ Intuitive does not, and cannot, guarantee that no EndoWrist will ever malfunction before it completes its last authorized use. The testing record that Dr. Rubach ignored contains extensive explanation and application of sophisticated statistical models designed to manage the risk of that happening.

tests,” *id.* ¶ 65, and describes in detail the nature, design, results, and documentation of that testing. *See id.* ¶¶ 66–72. As he summarizes, “Intuitive’s rigorous testing of its EndoWrist instruments adequately reflects the stresses and forces that instruments are subjected to during clinical use and demonstrates that instruments can only be reliably used a limited number of times.” *Id.* ¶ 18. Similarly, Intuitive’s expert Christy Foreman describes the process by which the FDA cleared Intuitive’s regulatory submissions for the da Vinci system, which included the testing data supporting EndoWrist use limits. *See id.* Ex. 5 ¶¶ 75–101.

Dr. Rubach simply ignored this evidence. At most, he saw “references” to Intuitive’s FDA submissions in a report by one of plaintiffs’ experts that was provided to him. *Id.* Ex. 3 at 118:9–119:4. But Dr. Rubach expressly *disclaimed* relying on that information, noting the report “did not form the basis for [his] opinions”—which is consistent with his admission that he is “not an expert in regulatory approvals.” *Id.* at 100:9–21, 119:5–11. In fact, Dr. Rubach candidly acknowledges in his report that he does “not know whether the use counter solves any safety or quality issues,” *id.* Ex. 1 ¶ 36, even though there is voluminous evidence in the record that it does exactly that.

Dr. Rubach’s reliance on a handful of personal observations and disregard of a robust and contrary body of scientific evidence fails several of Rule 702’s requirements. His opinions do not “fit” the facts of this case and are thus irrelevant. *See Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010) (“Expert opinion testimony is relevant if the knowledge underlying it has a valid connection to the pertinent inquiry.”) (citation omitted). Furthermore, his opinions are not based on sufficient facts. *See* Charles Alan Wright & Arthur R. Miller, *Federal Practice and Procedure* § 6268 Subdivision (b) (2d ed. 2022) (where an expert “‘cherry picks’ favorable data … but ignores a significant quantity of other important facts, the trial court would be justified in concluding that the expert’s testimony is not based on sufficient facts or data”). For the same reason, these opinions are also unreliable. *See In re Bextra & Celebrex Mktg. Sales Pracs. & Prod. Liab. Litig.*, 524 F. Supp. 2d 1166, 1176, 1184 (N.D. Cal. 2007) (excluding as unreliable the testimony of expert who “cherry-pick[ed]” evidence “that support his conclusion and reject[ed] or ignor[ed] the great weight of the evidence that contradicts his conclusion”).

In the end, Dr. Rubach’s reliance “on an anemic and one-sided set of facts” renders these opinions inadmissible. *Smith v. Illinois Dep’t of Trans.*, 936 F.3d 554, 558–59 (7th Cir. 2019).

B. Dr. Rubach’s Opinions Regarding the Alleged Arbitrariness of EndoWrist “Repair Restrictions” Lack Any Foundation in a Reliable Methodology.

Dr. Rubach opines that the “repair restrictions that Intuitive places on EndoWrists are arbitrary from a surgical perspective, and do not appear to advance any medical objectives.” Lannin Dec. Ex. 1 ¶ 35. Again, however, Dr. Rubach does not base this opinion on any scientific studies or other analysis. Instead, Dr. Rubach simply relies on a general perception that “the use of repaired surgical instruments is standard” and that “such instruments are in my experience safe and effective.” *Id.* ¶ 34. He further states that “there is no reason to treat EndoWrist instruments differently than their laparoscopic counterparts, which are used until they either cease to function effectively or show signs of likely imminent failure.” *Id.* ¶ 35; *see also id.* Ex. 2 ¶ 3(g), 7, 15–16, 18.

These opinions are flawed in multiple respects. To start, they lack factual support and are thus unreliable. The modification of EndoWrists to disable a safety protection built into the instrument that is at issue in this case is quite different from the everyday repairs or “tune ups” of completely *different* instruments that Dr. Rubach refers to, which did not alter the functioning of the instruments as they were originally designed and cleared by FDA. And although Dr. Rubach asserts that a “repaired” EndoWrist should be “safe and effective,” *see id.* Ex. 1 ¶ 34, ***he has never used one***, and he conceded at deposition that “without having personal experience, it’s very hard for me to comment on the[] effectiveness” of EndoWrists that had been “repaired” or “remanufactured.” *Id.* Ex. 3 at 106:17–107:21; *see also id.* Ex. 2 ¶ 5.⁴ Moreover, while Dr. Rubach opines that “there is no reason to treat EndoWrist instruments differently than their laparoscopic counterparts,” *id.* Ex. 1 ¶ 35, his report identifies no basis for this

⁴ At deposition, Dr. Rubach did claim to have used “instruments in training whose use counter was disabled,” Lannin Dec. Ex. 3 at 106:17–24, but that is inconsistent with his rebuttal report’s admission that he has not “used an EndoWrist that has had its use limit extended.” *Id.* Ex. 2 ¶ 5. Even if Dr. Rubach has used such an instrument “in training,” that experience is irrelevant given that his opinions concern the use of instruments in surgery.

claim, such as a description of how the two kinds of instruments are designed and engineered that would make the comparison he offers meaningful. When pressed on these points at deposition, Dr. Rubach reverted to a conclusory assertion that “EndoWrist instruments are structurally and functionally similar to their laparoscopic counterparts,” but that simply restates his premise. *Id.* Ex. 3 at 116:5–16; *see also id.* Ex. 2 ¶ 16. In the end, this opinion is nothing but *ipse dixit*.⁵

Dr. Rubach is also unqualified to offer these opinions comparing traditional laparoscopic instruments and EndoWrists. Certainly he is “not an engineer” who can “opine on how to repair instruments.” *See id.* Ex. 3 at 118:5–8; *see also id.* at 104:21–22. He knows “very little about material science.” *Id.* at 104:23–24. He conceded that he “cannot comment about the physical properties of durability of surgical instruments or DaVinci instruments.” *Id.* at 105:5–10.

Finally, these opinions do not fit the facts of his case. *See Primiano*, 598 F.3d at 565. As discussed above, Dr. Rubach’s discussion of “repaired” instruments refers to the routine maintenance of traditional laparoscopic instruments that do not have FDA-cleared use limits. That discussion is irrelevant to the remanufacturing of an EndoWrist to enable uses beyond its FDA-cleared limit.

In sum, Dr. Rubach’s opinion that EndoWrist “repair restrictions” are arbitrary do not satisfy the threshold standards for admissibility of expert opinion.

C. Dr. Rubach Is Not Qualified To Offer His Opinions as to Intuitive’s Alleged Dominance of a Purported Market for Minimally Invasive Robotic Surgery.

In his opening report, Dr. Rubach repeatedly opines that “[m]inimally invasive robotic surgery is dominated by a single manufacturer: Intuitive.” *See Lannin Dec. Ex. 1 ¶ 18; see also id. ¶ 21* (“Intuitive, with its da Vinci robot, is currently the dominant force in minimally invasive robotic surgery in the U.S.”); *id. ¶ 22* (The da Vinci “remains the dominant minimally invasive surgical robot to this

⁵ In his rebuttal report, Dr. Rubach suggests the burden was on *Intuitive*’s surgeon expert to “explain why third-party EndoWrist repair companies could not attain the same level of reliability and safety that has been achieved by Intuitive, or that has been achieved with servicing of other multi-use minimally invasive surgical instruments (some of which are quite complex).” Lannin Dec. Ex. 2 ¶ 7. Needless to say, Dr. Rubach cannot gloss over the factual holes in his own opinions by claiming it was Intuitive’s burden to introduce evidence refuting them.

day.”). In his rebuttal report, Dr. Rubach reiterates his opinion that Intuitive is the “dominant force in the US robotic surgery market.” *See id.* Ex. 2 ¶¶ 3(a), 19(a).

Dr. Rubach is not qualified to offer these opinions. While a properly qualified expert “may provide his expert economic opinion as to whether Defendants possessed market power,” Dr. Rubach is not an economics expert. *Sumotext Corp. v. Zoove, Inc.*, 2020 WL 533006, at *12 (N.D. Cal. Feb. 3, 2020); *see* Lannin Dec. Ex. 3 at 61:5–9 (conceding that he does “not consider [him]self as an expert in economics”). In fact, Dr. Rubach’s familiarity with economics is limited to a single undergraduate college course. *See id.* at 108:18–109:2. He readily conceded at deposition that he does not have any “training or education in the area of defining an antitrust market for a manufactured product.” *Id.* at 108:14–17. Moreover, opinions of this type must be supported by an economic analysis. *See Sumotext*, 2020 WL 533006, at *12. Dr. Rubach offers no such analysis, rendering his opinions unreliable as well. *See, e.g., Dep’t of Toxic Substances Control v. Technichem, Inc.*, 2016 WL 1029463, at *1 (N.D. Cal. Mar. 15, 2016) (Chhabria, J.) (excluding as unreliable an expert opinion that “does no more than regurgitate information given to him by other sources (including self-serving assertions by the [plaintiffs])”).

D. Dr. Rubach’s Expertise Gives Him No Basis for Opinions About the Purported Marketing and Recruiting Implications of the da Vinci System.

Dr. Rubach offers opinions about the purported marketing and recruiting implications for hospitals if they do or do not possess da Vinci systems. For example, he opines that “any hospital that wants to attract a modern minimally invasive surgeon to its staff must have at least one, and usually more than one, da Vinci robot.” Lannin Dec. Ex. 1 ¶ 23. He further opines that “U.S. hospitals that do not have a da Vinci robot find themselves at a great disadvantage in: (a) attracting well qualified surgeons who practice minimally invasive surgery, and (b) trying to appeal to patients seeking minimally invasive surgical treatments.” *Id.* ¶ 9; *see also id.* Ex. 2 ¶¶ 3(b), 19(b). In his opinion,

“having a da Vinci robot also creates a ‘halo effect’ for other hospital services, and can improve community and referring physician perceptions.” *Id.* Ex. 1 ¶ 24.

Dr. Rubach is not qualified to offer these opinions. He is not a marketing expert. *See id.* Ex. 3 at 30:12–20. Nor does he have any responsibility for hospital recruiting. *See id.* at 21:15–18 (testifying that his responsibilities as Vice Chair of Surgery at St. Francis Hospital do not “include any recruitment of physicians”).

Nor does Dr. Rubach offer a basis for any of these opinions. He does not bolster his slender to non-existent personal experience by citing to survey data or other reliable information that would support his sweeping general conclusions about the implications of the da Vinci for “hospitals.” At deposition, Dr. Rubach testified that his opinions about recruiting were based on his “interact[ions] with a lot of people,” that he has been personally “approached by recruiters,” and that he was recently involved in an effort to recruit a single surgeon. *See id.* at 55:14–56:9.

Dr. Rubach’s marketing opinions are based on similarly generic anecdotes. He explained that his patients “spend a lot of time[] researching their option[s]” and the “only way I could attract these people to my practice is if I offer all those options because if I do not, they will go someplace else.” *Id.* at 56:10–24. His opinions as to a “halo effect” are based on his “experience of living in the world of surgery that I’ve been referring to for the last two decades, interacting with my colleagues, going to conferences, reading articles, speaking to people, just generally being part of the world of surgery and particularly minimally invasive surgery.” *Id.* at 97:20–98:4.

These personal anecdotes and bromides about “speaking to people” are not a sufficient basis for Dr. Rubach’s sweeping opinions about how “U.S. hospitals” recruit surgeons and market themselves based on the da Vinci system, including his opinions as to the purported “halo effect” of having a da Vinci system.

E. Dr. Rubach’s Opinions About the Zeus Robot Are Nothing More Than Speculation and Hearsay, with No Application of Expertise.

Dr. Rubach offers various opinions about the “Zeus” robotic surgery system. All of these opinions are based on speculation and hearsay; none touch on even anecdotal personal knowledge on Dr. Rubach’s part, much less anything on which he is an expert.

Dr. Rubach states that “it is my understanding that Intuitive acquired Computer Motion, the manufacturer of a competing surgical robot called ‘Zeus,’” and that “the Zeus robot was phased out by Intuitive in favor of the da Vinci[.]” Lannin Dec. Ex. 1 ¶ 22. He describes the Zeus robot as “conceptually similar to the da Vinci” except that it included a “haptic feedback ability” that did not exist with the da Vinci. *Id.* In Dr. Rubach’s opinion, the lack of haptic feedback “has been a disappointing shortcoming of the da Vinci robot throughout its existence, and has been a source of widespread criticism by surgeons who use the da Vinci.” *Id.*

First, there is no basis for Dr. Rubach’s opinion that Intuitive “phased out” the Zeus robot “in favor of the da Vinci.” He cites no evidence for this assertion. At deposition, Dr. Rubach explained that it “goes back to the time where Zeus was one of the market players” and that “at some point, one of the manufacturers bought the second one and essentially phased out the product.” *See id.* Ex. 3 at 109:25–110:11. But this testimony merely repeats his report; left unexplained is how Dr. Rubach purports to *know* Intuitive purportedly “phased out” the Zeus robot in favor of the da Vinci. This is sheer speculation and—at best—hearsay on his part, with no application of any surgical expertise. *See Dep’t of Toxic Substances Control*, 2016 WL 1029463, at *1 (“speculative testimony is inherently unreliable”).

Second, there is no basis for Dr. Rubach’s opinions as to the design and features of the Zeus robot, including the alleged “haptic feedback” ability. He has never used a Zeus robot. *See Lannin Dec.* Ex. 3 at 109:5–7. He did watch a video of other surgeons using the Zeus robot, and he may have seen another surgeon use the Zeus robot at another hospital where he once worked. *See id.* at 109:8–24. He recalls once long ago investigating the “pros and cons” of the Zeus robot, but “the details of those investigations escape [him] because they were from decades ago.” *Id.* at 110:12–20. None of this

provides a basis for Dr. Rubach to offer expert opinions about the Zeus robot or compare it to the da Vinci.

Finally, Dr. Rubach may not opine that the da Vinci system’s alleged lack of haptic feedback ability “has been a source of widespread criticism by surgeons who use the da Vinci.” *Id.* Ex. 1 ¶ 22. Dr. Rubach’s report does not describe how he knows what “surgeons” in general think about the lack of haptic feedback. He certainly does not claim to have performed or reviewed any scientific survey on that point. Rather, he testified that he relied on his own experience as well as “conversations with surgeons like myself,” and that he has “spoken to many people about it.” *See id.* Ex. 3 at 114:8–115:12.

These alleged anecdotal “conversations” are an insufficient basis for an expert opinion that there is “widespread criticism” voiced by “surgeons who use the da Vinci.” Indeed, the court in the *Rebotix* action in Florida excluded certain surgeon opinions on the same basis. There, the court concluded the surgeon could not opine as what “surgeons, patients, and/or payors” thought about reset EndoWrists, reasoning the surgeon had “not used any method to learn of the perceptions of these other groups,” such as “conduct[ing] any surveys or polls” or “read[ing] any report about how other physicians felt about the repair process.” *See Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, 2022 WL 3226769, at *4 (M.D. Fla. Aug. 10, 2022). Similarly here, because Dr. Rubach’s “own experience is not a sufficient basis to permit him to testify as to what other doctors might think,” his testimony as to other surgeons’ alleged criticisms of the da Vinci system should be excluded. *See id.*⁶

F. Dr. Rubach’s Opinions As to Physicians’ Practice of “Off-Label Use” Are Both Irrelevant and Unreliable.

Finally, for the first time in his rebuttal report Dr. Rubach offers the sweeping opinion that “physicians” and “doctors” often use medical products in ways that go beyond the “recommendations of manufacturers and the FDA.” Lannin Dec. Ex. 2 ¶ 12. He opines, for example, that “physicians often go beyond the recommendations of manufacturers and the FDA and rely on other clinical expertise or

⁶ In *Rebotix*, the Court did not exclude the surgeon’s testimony entirely, leaving open his ability to testify about his *own* experience. *See Rebotix*, 2022 WL 3226769, at *3–4. Since Dr. Rubach has no personal experience with the Zeus system, this exception would not apply to him.

evidence,” which is embodied in the practice of “off-label use.” *Id.* He asserts that “clinical judgement and experience dictates” that “we as doctors sometimes make treatment recommendations that are beyond the limits adopted by the manufacturer and cleared by the FDA.” *Id.* ¶ 14.

To start, Dr. Rubach’s opinions are irrelevant. The sort of routine “off-label use” to which Dr. Rubach is referring—where a drug or device may be used for procedures or conditions other than the specific ones (*e.g.*, colorectal surgery) for which it is approved—is entirely different from the facts presented in this case, which involves the use of an EndoWrist in a way that its clearance, which includes use limits, implicitly prohibits. Dr. Rubach cites no support for the proposition that *this* type of “off-label use” of a reset EndoWrist would meet with the acceptance and approval of the medical community. That lack of fit requires the exclusion of these opinions. *See Primiano*, 598 F.3d at 565.

In addition, Dr. Rubach’s sole claimed basis to speak on behalf of “physicians” and “doctors” is his own alleged experience using a robotic instrument “off-label,” *see Lannin Dec. Ex. 2 ¶ 13*, and a single medical organization’s alleged endorsement of using one drug “off-label.” *Id.* ¶ 12. Neither provides a basis for his testimony on behalf of doctors everywhere; certainly he does not claim to have reviewed any reliable evidence, such as survey data, as to physicians’ comfort with off-label use (much less use of a reset EndoWrist). As such, these unreliable opinions should be excluded. *See Rebotix*, 2022 WL 3226769, at *4; *see, e.g., Bartlett v. Mut. Pharm. Co.*, 742 F. Supp. 2d 182, 195 (D.N.H. 2010) (observing “most courts have prohibited experts from testifying … about ‘what doctors generally think,’ unless the testimony is based on something more reliable than simply the expert’s own experience as a doctor”) (collecting cases).

IV. CONCLUSION

For the foregoing reasons, the Court should grant this Motion and exclude the following of Dr. Rubach’s opinions:

- The alleged arbitrariness of EndoWrist use limits. *See Lannin Dec. Ex. 1 ¶¶ 12, 28–33, 35–36; id. Ex. 2 ¶¶ 3(e), 4–9, 30.*
- The alleged arbitrariness of EndoWrist “repair restrictions.” *See id. Ex. 1 ¶¶ 34–35; id. Ex. 2 ¶¶ 3(g), 7, 15–16, 18.*

- Intuitive's purported dominance of an alleged market for minimally invasive robotic surgery. *See id.* Ex. 1 ¶¶ 18, 21–23; *id.* Ex. 2 ¶¶ 3(a), 19(a).
- The marketing and recruiting implications for hospitals of having a da Vinci system. *See id.* Ex. 1 ¶¶ 9, 23–24; *id.* Ex. 2 ¶¶ 3(b), 9(b).
- The features of an earlier-generation “Zeus” robot and surgeons’ supposed “widespread criticism” that the da Vinci system lacks that robot’s tactile feedback functionality. *See id.* Ex. 1 ¶ 22.
- How physicians and doctors supposedly practice “off-label use.” *See id.* Ex. 2 ¶¶ 12–14.

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